Remarks

Claims 4-6 are amended herein. Support for the amendment of claims 4-6 can be found throughout the specification, for example at page 15, line 21 to page 16, line 2. Claims 4-5 are also amended to correct form.

New claims 13 and 14 are added. New claims 13 and 14 depend from claim 4, and are directed to two alternative embodiments recited previously in claim 4.

Applicants believe no new matter is added. Reconsideration of the subject application is respectfully requested.

Restriction Requirement

Applicants acknowledge the election of Group II, a vaccine comprising an immunogenic amount of a protein of 16 kDa of *Piscirickettsia salmonis* and the election of the species A, SEQ ID NO: 2. It is the Applicants' understanding that if a generic claim is considered to be allowable, Applicants will be entitled to the examination of the additional species (polypeptides comprising an amino acid sequence set forth as SEQ ID NO:4 and SEQ ID NO: 6).

Specification

The specification is objected to for not complying with the requirements of 37 C.F.R. § 1.821-1.825. Applicants have amended the specification to conform with these requirements, thereby overcoming the objection.

The specification is objected to for the use of trademarks on page 31, without appropriate capitalization. The specification is amended herein as requested, thereby removing the objection.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 4-6 are rejected as allegedly not being enabling for a vaccine comprising an immunogenic amount of a protein of 16 kDa as determined by SDS-PAGE, wherein the protein is a fragment or a variant of SEQ ID NO: 2. Applicants respectfully disagree with this rejection, and submit that fragments and variants are fully enabled by the specification.

However, in order to advance prosecution, claims 5-6 have been amended to no longer recite the use of fragments or variants. The Office action states that the specification is enabling for a vaccine comprising an immunogenic amount of a protein of 16 kDa as determined by SDSPAGE, said protein comprising the amino acid sequence as set forth in SEQ ID NO 2. Thus, the Applicants submit that the amendments to claims 5-6 remove the objection. Applicants believe that the amendments do not alter claim scope. Applicants reserve the right to pursue any canceled subject matter in a continuation application.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 4-6 are rejected as claim 4 allegedly not including antecedent basis for the recitation of "variants" in claim 5. Claim 5 is amended herein to remove the word "variants," rendering the rejection moot.

Rejections Under 35 U.S.C. § 102(b)

Claim 4 is rejected as allegedly being anticipated by Smith et al. (*Devel. Biol. Stand.* 90: 161-166, 1997). Applicants respectfully disagree with this rejection as applied to claim 4 as amended.

Smith et al. teaches standardization of challenge methods against *Piscirickettsiosis*. Formalin killed bacterins were injected into coho salmon wherein *Piscirickettsiosis* occurred. Bacterins were prepared from the LF-89 strain of *P. salmonis* cultured in CHSE-214 cells incubated until the cytopathic effect was complete. Infectious supernatants were clarified by centrifugation and then titred by endpoint dilution. Organisms contained in the culture medium were killed in 1% formalin and diluted in PBS to produce the final bacterin used in the studies (see page 163, last paragraph). Some of the fish groups vaccinated with the formalin killed bacterins experienced lower cumulative mortality than the non-vaccinated control group. However, Smith et al. concludes that the use of bacterins is variable, and that inconsistent experimental results were achieved. Smith et al. further states that genetic and antigenic variation among different *P. salmonis* isolates could be important in future strategies (see "Conclusions," page 165).

Smith et al. teaches that the development of safe and effective vaccines against rickettsial agents is "variable." All of the vaccine trials described in Smith et al. utilized formalin killed *P. salmonis.*

Smith et al. does not teach the use of an immunogenic amount of any isolated protein in a vaccine against *Piscirickettsiosis,* let alone the use of a protein of 16 kDa isolated from *P. salmonis.* In addition, Smith et al. does not teach the sequence of any proteins isolated from *P. salmonis*, let alone a protein including an amino acid sequence set forth as SEQ ID NO: 2. Clearly, Smith et al. does not teach, nor render obvious, the use of an immunogenic amount of an isolated protein of 16 kDa as determined by SDS PAGE, including an amino acid sequence of one of SEQ ID NO: 2, SEQ ID NO: 4, or SEQ ID NO: 6, for fish for protecting a poikilothermic fish against infection by the bacterial pathogen *P. salmonis.* Thus, Applicants submit claims 4-6 are not anticipated, or rendered obvious, by Smith et al.

In view of these remarks, and the amendment of the claims, reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

Applicants submit that the pending claims are in condition for allowance, which action is requested. If any matters remain to be addressed before a Notice of Allowance is issued, Applicants request that Examiner Ford contact the undersigned for telephone interview at the number listed below.

Respectfully submitted,

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